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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,651	07/09/2003	Pu Zhou	1001.1662101	9310

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EXAMINER

HUSON, MONICA ANNE

ART UNIT PAPER NUMBER

1732

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,651	<b>Applicant(s)</b> ZHOU, PU	
	<b>Examiner</b> Monica A. Huson	<b>Art Unit</b> 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 35-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to the Amendment filed 24 May 2006.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 13, and 35-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Noone et al. (U.S. Patent 6,591,472).

Regarding Claim 1, Noone et al., hereafter "Noone," show that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (Figures 5-6); and subsequent to cutting through the braid layer and the inner lubricious layer, securing a second polymer over the braid layer, the second polymer segment extending over the first polymer segment and extending

distally of the cutting position (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 11, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip (Figure 8, element 75, 145).

Regarding Claim 13, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70).

Regarding Claim 35, Noone shows that it is known to carry out a method of forming a catheter (Abstract), comprising cutting a catheter subassembly at a cutting location (Figure 5, location 125), the subassembly having proximal and distal ends, an inner layer (Figure 5, element 65), a reinforcement layer on the inner layer (Figure 5, element 70), and a securement layer disposed over at least a portion of the reinforcement layer (Figure 5, element 100); removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location (Figure 6); and subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment extends distally of the cutting location (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 36, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising forming

a portion of the polymeric outer segment into a distal tip for the catheter (Figure 8, element 25).

Regarding Claim 37, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising assembling the catheter subassembly by providing an inner subassembly having the reinforcement layer disposed on the inner layer (Figure 5, elements 65, 70); and disposing the securement layer on the inner subassembly by securing a securement segment thereon (Figure 5, element 100).

Regarding Claim 38, Noone shows the process as claimed as discussed in the rejection of Claim 37 above, including a method wherein the reinforcement layer has a distal end, the securement layer has a distal end, and the step of disposing the securement layer on the inner subassembly is performed such that the distal end of the reinforcement layer extends distally beyond the distal end of the securement segment (Figure 5, elements 70, 100).

Regarding Claim 39, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method wherein the reinforcement layer comprises a braided member (Column 8, lines 49-51).

Regarding Claim 40, Noone shows that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end (Column 8, lines 33-34, 49-50); positioning an inner lubricious liner within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting location proximal of the distal end of the braid layer, thereby forming a catheter subassembly including the inner lubricious liner, the braid layer, and the first polymer segment, the catheter subassembly having a distal end defined at the cutting location (Figures 5-6); and securing a second polymer over the catheter subassembly, the second polymer segment extending over the

first polymer segment of the catheter assembly and extending distally of the distal end of the catheter subassembly (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61), wherein the step of securing the second polymer segment over the catheter subassembly is performed subsequent to the step of cutting through the braid layer (Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 41, Noone shows the process as claimed as discussed in the rejection of Claim 40 above, including a method wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, 7, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone, in view of Wilson (U.S. Patent 5,951,929).

Regarding Claim 2, Noone teaches the invention of claim 1 as discussed above, but does not expressly teach that the first polymer segment has a melting point that is at least about 10°F above a melting point of the second polymer segment. Wilson teaches using a blend of PEBA and approximately 30% BASO<sub>4</sub> (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). Thus, Wilson teaches that the first polymer segment has a melting

point that is at least 10<sup>0</sup>F (25<sup>0</sup>F) above the melting point of the second polymer segment. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's materials during Noone's method in order that the first polymer segment will not remelt upon application of the second polymer segment (Wilson, column 9, lines 41-50).

Regarding Claim 3, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (Column 7, lines 57-67; Column 8, lines 1-5). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 4, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer but not enough heat to melt the first polymer segment (Column 8, lines 52-65). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 5, Noone shows the process as claimed as discussed in the rejection of Claims 1 and 4 above, but he does not show specific melting points. Wilson teaches that the first polymer segment has a melting point that is greater than about 400<sup>0</sup>F and the second polymer segment has a melting point that is less than about 400<sup>0</sup>F. Wilson teaches using a blend of PEBA and approximately 30% BASO<sub>4</sub> (column 8, lines 32-33), which melts at a range of

Art Unit: 1732

385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 7, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the first polymer segment comprises a polyether-ester elastomer (column 9, lines 20-25). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 9, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 10, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Wilson, further in view of Zadno-Azizi (US 2004/0015150). Noone teaches the invention of claim 4 as discussed above, but fails to explicitly teach that the second polymer segment has a melting point that is about 350°F. Zadno-Azizi teaches a catheter outer coating (PEBAX) that has a melting point at about 350°F (paragraph 0177). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a material with Zadno-Azizi's specific melting point for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone, in view of Ashiya et al (5,947,925), as stated in the paper mailed 21 September 2005. Noone teaches the invention of claim 1 as discussed above but fails to explicitly teach that the second polymer segment comprises a acetal resin/polyurethane blend. Ashiya et al., hereafter "Ashiya," teaches the second polymer segment comprises an acetal resin/polyurethane blend (column 6, lines 40-61, polyoxymethylene is an acetal resin). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Ashiya's specific material for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

### ***Response to Arguments***

Applicant's arguments filed 24 May 2006 have been fully considered but they are not persuasive.

Applicant contends that Noone does not show the instant invention because he does not show securing a second polymer segment over the braid layer subsequent to cutting through the braid layer and the inner lubricious layer. This is not persuasive because it is believed that Noone does, in fact,

show this limitation. At Column 12, lines 9-11, Noone describes the cutting of the braid layer and the inner lubricious layer. At Column 12, lines 35-37, Noone describes removing the cut section. At Column 12, lines 52-61, Noone describes attaching a soft tip to the cut end of the catheter. The soft tip comprises a polymer segment, and therefore, Noone does, in fact, teach securing a polymer segment over the braid layer at a time subsequent to cutting through the braid layer and the inner lubricious layer.

Applicant contends that all other claims are patentable for the same reasons as claim 1, and any other references that were cited in claim-specific rejections do not cure the alleged deficiencies of Noone. Since it is the position of the examiner that Noone does, in fact, show the claimed invention, the rejections of all other claims are maintained as originally stated.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

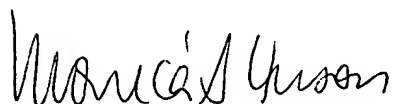
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone

Art Unit: 1732

number is 571-272-1198. The examiner can normally be reached on Monday-Friday 6:45am-3:15pm.

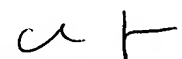
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Monica A Huson

July 28, 2006

  
**CHRISTINA JOHNSON**  
**PRIMARY EXAMINER**

7/31/06